HONORABLE RONALD B. LEIGHTON

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

INTERNATIONAL REHABILITATIVE SCIENCES, INC., d/b/a RS MEDICAL, a Washington corporation, Plaintiff, v. KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services, Defendant.	Case No. C08-5442RBL ORDER ON MOTIONS FOR SUMMARY JUDGMENT [Dkt. #s 65 and 66]

THIS MATTER comes before the Court on Plaintiff's Motion for Summary Judgment and Defendant's Cross-Motion for Summary Judgment [Dkt. #s 65 and 66].

Plaintiff International Rehabilitative Sciences, Inc. ("RS Medical") seeks reversal of four final decisions:

1. ALJ Appeal Numbers 1-195779535, 1-180164901, and 1-201743101 (originally issued April 11, 2008, amended May 12, 2008) ("535 Decision").

2. ALJ Appeal Number 1-16054549 (issued May 14, 2008) ("549 Decision").

3. ALJ Appeal Number 1-160448416 (issued May 14, 2008) ("416 Decision").

4. ALJ Appeal Number 1-173420782 (originally issued April 9, 2008, amended May 28, 2008) ("782 Decision").

Those decisions, rendered in May 2008 by the Medicare Appeals Council, acting under the authority of the Secretary of the Department of Health and Human Services ("Secretary"), denied coverage or payment of Medicare claims submitted for provision of the BIO-1000, a device for treatment of osteoarthritis of the knee. Defendant Secretary Kathleen Sebelius asks that the Court affirm those decisions.

The Court has reviewed the parties' briefing and submitted excerpts from the administrative record. For the reasons stated below, Plaintiff RS Medical's motion for summary judgment [Dkt. # 65] is GRANTED and Defendant's cross-motion for summary judgment [Dkt. #66] is DENIED.

I. BACKGROUND

A. Medicare Coverage and Payment Claims Determinations

Medicare is a federally funded health insurance program for the elderly and disabled that was established by Congress under Title XVIII of the Social Security Act. 42 U.S.C. §1395 *et seq*. Part B of the Medicare statute authorizes payments for outpatient care and provision of durable medical equipment[1] like the device at issue here. *See* 42 U.S.C. §§ 1395k(a)(1), 1395m(j), 1395x(n). *See also* 42 C.F.R. Part 410 (scope of Part B benefits). However, this payment authority is subject to a number of exclusions, most notably a general bar on payment for items and services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

The Secretary is given significant discretion under 42 U.S.C. § 1395ff(a) to make initial determinations regarding whether items and procedures will be covered by Medicare. *See Heckler v. Ringer*, 466 U.S. 602, 617 (1984). The Secretary may administer coverage determinations in a variety of ways. She

[1]The parties use the acronym "DME" to refer to durable medical equipment. In an effort to avoid inundating this opinion with the same alphabet soup that flooded the parties' briefing, the Court will refrain from using this and many other acronyms and abbreviations utilized by the parties (NCD, LCD, HCPCS, ABN, MAC, DMAC, etc.), with the exception of the acronyms for the administrative bodies involved (Department of Health and Human Services ("HHS"), Food and Drug Administration ("FDA") and Centers for Medicare & Medicaid Services ("CMS")) and device names ("BIO-1000," "TENS").

may issue a "national coverage determination" as to whether a service or item is covered nationally. 42 U.S.C. § 1395ff(f)(1). Alternatively, a local Medicare contractor may issue a "local coverage determination" as to whether a service or item is covered within that contractor's limited jurisdiction. 42 U.S.C. § 1395ff(f)(2). When, as here, coverage of an item or service is not governed by a national or local coverage determination, the regional contractor responsible for administering benefits claims determines whether the "not reasonable and necessary" exclusion applies to individual claims. 68 Fed. Reg. 63692, 63693 (Sept. 26, 2003) (final rule).

Where coverage is determined to be unavailable under the "not reasonable and necessary" exclusion, Medicare is nonetheless required to hold the provider and beneficiary harmless and make payment if neither knew, or could have been reasonably expected to know, that coverage was unavailable. 42 U.S.C. § 1395pp(a). Additionally, where providers know that coverage is likely to be denied, they can shift liability for non-covered services and items to beneficiaries by providing them with an advance beneficiary notice informing them of the probable denial. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.404(b); *Medicare Claims Processing Manual*, CMS Publication 100-04, § 40.1.1.

A party dissatisfied with a regional contractor's benefits determination must work its way through several layers of appeals. *See* 42 U.S.C. § 1395ff. The party must first request a "redetermination" by the contractor, then a "reconsideration" by a qualified independent contractor, then a review by an administrative law judge. 42 U.S.C. § 1395ff(a)-(c); 42 C.F.R. § 405.920, .940, .960, .1002. The Medicare Appeals Council is the highest level of administrative appeal, and may review the decision of an administrative law judge on appeal by a party or on its own motion. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1100, .1110. A party may seek judicial review of a final decision of an administrative law judge or the Medicare Appeals Council under 42 U.S.C. § 405(g) and 5 U.S.C. § 706.

B. Factual Background

The underlying facts in the case are largely undisputed and are recorded in the 22,269 page

Administrative Record ("AR"). Plaintiff RS Medical was a Medicare participating supplier of durable medical equipment from August 1993 through December 2007. The claims at issue relate to RS Medical's distribution of the Bionicare Stimulator System, Model 1000 ("BIO-1000") between June 2005 and March 2007. The BIO-1000 is a transcutaneous electrical joint stimulation device that received FDA clearance for marketing as a "Class II" medical device in July 1997. The FDA's clearance was based on the device's substantial similarity to another legally marketed device, the transcutaneous electrical nerve stimulator ("TENS"). The letter granting clearance stated that the BIO-1000 was "indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee."

Beginning in 2004, Bionicare Medical Technologies, Inc. ("Bionicare"), the BIO-1000's manufacturer, began submitting claims for Medicare reimbursement for the device. In February 2005, RS Medical contracted with Bionicare to begin distributing the device as well. The vast majority of Medicare claims submitted in 2004 and 2005 were initially denied. AR 19135-19137. Some of these claims, although how many is disputed, were later paid following appeal. *See* AR 20718-20894. Bionicare attributed many of these early denials to the fact that they were being billed under a miscellaneous code in the Healthcare Common Procedure Coding System, a system of codes used to process both Medicare and many private sector health care billing claims. AR 19137. Bionicare subsequently requested and received from CMS a set of unique billing codes for the BIO-1000 and its supplies, which became effective January 1, 2006. AR 20519-20.

In 2006, the year that most of the claims at issue were submitted, RS Medical and Bionicare began to receive an increasing number of favorable Medicare coverage and payment determinations. Though there is some dispute as to just how many claims were successfully pursued, it is clear that favorable determinations began to be issued at both the initial contractor level and at several levels of appeal, including favorable decisions from administrative law judges. *See* AR 19321, 20700, 20718-894, 21013-021. As the favorable decisions were neither appealed by Bionicare or RS Medical nor taken up *sua sponte* by the Medicare

Appeals Council, they eventually became final decisions.

However, it is undisputed that the Medicare Appeals Council did not issue a decision on coverage of the BIO-1000 during the relevant period, nor does the record reflect that the Medicare Appeals Council has ever entered a favorable ruling on coverage of the BIO-1000. The record also does not establish that either Bionicare or RS Medical ever requested that the Secretary issue a national coverage determination for the BIO-1000.

The decisions at issue here were the result of claims that were denied and appealed at each level through the Medicare Appeals Council. To bolster their claims, RS Medical offered into the record extensive documentation in support of the medical necessity of the BIO-1000. For each beneficiary and claim, they secured a statement of medical necessity from the treating physician, including documentation that demonstrated that the beneficiary suffered from osteoarthritis of the knee. *See* Plaintiff's Statement of Material Facts, Dkt. # 65, ¶¶ 27-28 and accompanying cites to AR.

RS Medical further offered a number of studies and papers supporting the effectiveness of the BIO-1000 in treating the symptoms of osteoarthritis, as well as some studies suggesting that the BIO-1000 may stimulate cartilage growth, thereby addressing the underlying cause of these symptoms. *See* AR 20529-581. All of these offerings included among their authors at least one individual affiliated with Bionicare, and several of the studies were funded by Bionicare. Nonetheless, a number of them were published in peer-reviewed journals, although two were not published until after the dates of service at issue. Finally, in order to cover its bases, RS Medical also had each beneficiary sign an advance beneficiary notice acknowledging that Medicare was unlikely to pay the cost of the BIO-1000. One version of this notice advised that Medicare would likely not cover the device because it was new and "may be considered experimental." AR 19664. A second version of the notice simply advised that Medicare would probably not pay because "Medicare has not established coverage criteria for this item or does not cover this item." AR 16528.

Despite RS Medical's efforts, all four decisions of the Medicare Appeals Council denied the claims

for coverage of the BIO-1000 and related supplies, finding that it had not been shown to be reasonable and medically necessary for treatment of osteoarthritis. All four final decisions, issued between May 12 and May 28, 2008, were based on the same arguments. *See* AR 00001-17, 19197-207, 19208-218, and 19983-989. The Council mainly concluded that Bionicare and RS Medical had failed to conclusively demonstrate that the device was not experimental or investigational, leaving its necessity and reasonableness for treatment of osteoarthritis questionable. AR 00012-14, 19200-205, 19211-216, 19987. The findings were not based on the device's unsuitability for the treatment of any individual beneficiary, but rather purely on uncertainty surrounding the efficacy of the device for treatment of osteoarthritis. *See id.*

The Council did find that some of the advance beneficiary notices furnished by RS Medical were sufficient to shift liability for the cost of the device to the beneficiary. AR 00016, 19206, 19989. However, it found that the second version of the advance beneficiary notice was "generic" because the statement that "Medicare [had] not established coverage criteria" did not sufficiently alert beneficiaries to the reason that coverage was likely to be denied. AR 00015, 19218. The Council therefore found the notice to be defective and RS Medical to be liable for the cost of the device on claims where it had furnished that version to beneficiaries.

II. DISCUSSION

RS Medical argues that summary judgment reversing the Secretary's decisions should be granted on a number of grounds. First, it argues that, in light of favorable coverage decisions granted in upwards of 10,000 other medically indistinguishable claims for the BIO-1000, the Secretary's denials in these decisions are too inconsistent to merit deference to agency expertise. Second, it argues that the Secretary's findings that the BIO-1000 is not reasonable and medically necessary under 42 U.S.C. §1395y(a)(1) are arbitrary, capricious, and not based on substantial evidence. Finally, RS Medical argues that it should be held harmless under 42 U.S.C. § 1395pp because the shifting patterns of coverage made it impossible to know whether coverage would be granted or denied, or, alternatively, because it adequately warned beneficiaries that the

BIO-1000 might not be covered by Medicare.[2]

Defendant Kathleen Sebelius, acting Secretary of the Department of Health and Human Services, argues RS Medical's Motion should be denied and her own Cross-Motion for Summary Judgment granted. First, the Secretary argues that agency consistency should be measured only by final decisions rendered after appeal to the Medicare Appeals Council, and that any inconsistency between the challenged coverage decisions and decisions made at lower levels should be excused due to the massive nature of the Medicare program. Second, she argues that she is traditionally afforded broad discretion in coverage decisions, and that her finding that the BIO-1000 is not reasonable and medically necessary is supported by substantial evidence. Finally, the Secretary argues that RS Medical knew or should have known that the BIO-1000 would not be covered, as evidenced by its routine use of advance beneficiary notices, and this knowledge pushes the subject claims beyond the parameters of the hold harmless provisions of the Medicare statute and implementing regulations.

The Court reviews decisions of the Medicare Appeals Council under 42 U.S.C. § 1395ff(b), which incorporates 42 U.S.C. § 405(g), and 5 U.S.C. § 706. *Maximum Comfort Inc. v. Sec'y of HHS*, 512 F.3d 1081, 1084 (9th Cir. 2007). The decisions are reviewed to determine whether they were "arbitrary, capricious, an abuse of discretion, not in accordance with the law, or unsupported by substantial evidence on the record taken as a whole." *Wilmot Psychiatric/Medicenter Tucson v. Shalala*, 11 F.3d 1505, 1506 (9th Cir. 1993).

Summary judgment is appropriate when, viewing the facts in the light most favorable to the nonmoving party, there is no genuine issue of material fact which would preclude summary judgment as a matter of law. Once the moving party has satisfied its burden, it is entitled to summary judgment if the non-moving party fails to present, by affidavits, depositions, answers to interrogatories, or admissions on file,

[2]If successful, RS Medical's first argument, that it was impossible to know whether coverage would be provided, would force Medicare to pay the claims. Its latter argument, that the advance beneficiary notices were adequate, would simply allow RS Medical to shift liability to the beneficiaries.

"specific facts showing that there is a genuine issue for trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986). "The mere existence of a scintilla of evidence in support of the non-moving party's position is not sufficient." *Triton Energy Corp. v. Square D Co.*, 68 F.3d 1216, 1221 (9th Cir. 1995). Factual disputes whose resolution would not affect the outcome of the suit are irrelevant to the consideration of a motion for summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In other words, "summary judgment should be granted where the nonmoving party fails to offer evidence from which a reasonable jury could return a verdict in its favor." *Triton Energy*, 68 F.3d at 1221.

This Court does not weigh the evidence or determine the truth of the matter, but only determines whether there is a genuine issue for trial. *Anderson*, 477 U.S. at 249. Thus, the record below is examined only to resolve the question of whether either party is entitled to judgment on the undisputed facts.

A. Inconsistency with Other Coverage Decisions

RS Medical first urges the Court to refuse to defer to the Secretary's decisions because they are shown to be arbitrary and capricious by their inconsistency with thousands of other cases in which Medicare has covered and paid for the BIO-1000. The Secretary responds that the Medicare Appeals Council, as the highest adjudicatory body in the CMS system, has consistently denied coverage for the BIO-1000, and that its decisions should not be overturned simply because lower level decision-makers have made contrary decisions.

On one hand, an entitlement system on the scale of Medicare administers so many claims that perfect consistency may be unattainable; the key inquiry is whether there is consistency among final agency actions:

> [T]he Department of Health and Human Services is a mammoth bureaucracy with seemingly endless layers of internal review . . . "The Secretary's position" is the position of the Department as an entity, and the fact that people in the chain of command have expressed divergent views does not diminish the effect of the agency's resolution of those disputes. An inconsistent administrative position means flip-flops by the agency over time, rather than reversals within the bureaucratic pyramid.

Homemakers N. Shore, Inc. v. Bowen, 832 F.2d 408, 413 (7th Cir. 1987) (citations omitted). On the other hand, consistent treatment of similar cases must be more than an aspiration for agency adjudications. "The treatment of cases A and B, where the two cases are functionally indistinguishable, must be consistent. That

is the very meaning of the arbitrary and capricious standard." *Indep. Petroleum Ass'n of America v. Babbitt*, 92 F.3d 1248, 1260 (D.C. Cir. 1996).

In order to prevail on the basis of inconsistent treatment, a party must bring before the court "sufficient particulars of how the [plaintiff] was situated, how the allegedly favored party was situated, and how such similarities as may exist dictate similar treatment and how such dissimilarities as may exist are irrelevant or outweighed." *P.I.A. Michigan City, Inc. v. Thompson*, 292 F.3d 820, 826 (D.C. Cir. 2002). However, once a plaintiff has demonstrated these particulars of agency inconsistency, the agency must offer a considered explanation of the policy behind the inconsistency for its interpretation to receive the deference normally accorded reasonable agency interpretations. *Malcomb v. Island Creek Coal Co.*, 15 F.3d 364, 369 (4th Cir. 1994). While a court must normally give great weight to an agency's interpretation of its governing statute, unexplained inconsistency in that interpretation greatly reduces the deference it is owed. *BankAmerica Corp. v. United States*, 462 U.S. 122, 130 (1983).

RS Medical has clearly made out a case of agency inconsistency. It has submitted evidence showing that there have been favorable decisions on the BIO-1000 rendered from the initial stage up through the administrative law judge level; in short, every level but the Medicare Appeals Council. AR 20705-717 (showing initial payments), 20718-894 (favorable determinations of Administrative Law Judges). It has shown that favorable determinations were entered both before and after the claims at issue here were denied. Favorable determinations at the initial level became commonplace in 2006. AR 20903. An administrative law judge entered a favorable determination as early as February of that year. AR 20718-732. Thousands of favorable determinations have been entered since. AR 20906. The Secretary cannot therefore claim that the inconsistency is the result of new information that was unavailable as of the date of these denials. Similarly, the Secretary cannot claim that the inconsistency is the result of factual distinctions between the denials and the favorably-determined claims. Nothing in the record distinguishes them aside from when, where, and by whom they were decided. The Secretary has insinuated that some of the favorable decisions

in the record may not have been final, but has not offered even a scintilla of evidence to show otherwise. Lacking intervention by the Secretary, the finality of those decisions is inevitable.

The Secretary's argument that consistency should be measured only by the decisions of the Medicare Appeals Council is unavailing. By her logic, if contractors paid 999 out of 1000 claims for a device, and that sole denial was appealed and denied all the way through the Medicare Appeals Council, that claimant could still not make out a case for agency capriciousness simply because the Council had not contradicted itself. The flaws in this logic are obvious. After all, "the Secretary's position is the position of the Department *as an entity*," not merely the position of the Medicare Appeals Council. *Homemakers*, 832 F.2d at 413.

To explain away the inconsistency, the Secretary has offered only the consistency of the position taken by the Medicare Appeals Council, along with a suggestion that the claims system is so vast as to escape complete monitoring. While RS Medical has submitted extensive statistics showing the frequency with which payment has been made for the BIO-1000, the Secretary, rather than refuting these with contrary statistics, has offered statistics showing the number of claims dealt with by the Medicare system in recent years. This only causes the Court to question her choice of means for determining coverage.

The Secretary clearly has the tools available to shore up inconsistency throughout the coverage system. She could issue a national coverage determination, direct the regional carriers to issue local coverage determinations, or have the Council *sua sponte* take up and reverse administrative law judge decisions calling for coverage of the BIO-1000. Rather than do any of these things, she has allowed countless claims to be paid, while only ensuring that those reaching the top of the appeals pyramid are denied. This has led directly to the uncertainty faced by RS Medical and repeated provision of payment for a device the Secretary here argues is unnecessary. While the Secretary certainly has the authority to determine coverage through individual adjudications, and the Court will defer to her choice, selection of this means does not absolve her of responsibility for ensuring consistent results.

The Secretary's decisions describe a basis for finding that the BIO-1000 is not reasonable and

medically necessary. However, they offer no basis for differentiating between the claims denied and the numerous claims that RS Medical has shown were covered and paid. "Unexplained inconsistency is, at most, a reason for holding an interpretation to be an arbitrary and capricious change from agency practice under the Administrative Procedure Act." *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Serv.*, 545 U.S. 967, 981 (2005). However,

> such inconsistency provides a basis for rejecting an agency's interpretation only in "rare instances, such as when an agency provides no explanation at all for a change in policy, or when its explanation is so unclear or contradictory that we are left in doubt as to the reason for the change in direction."

Marmolejo-Campos v. Holder, 558 F.3d 903, 914 (9th Cir. 2009), *quoting* Morales-Izquierdo v. Gonzales, 486 F.3d 484, 493 (9th Cir.2007). Because this appears to be one of those "rare instances," the Secretary's decisions are entitled to no deference.

B. The Secretary's Decision Not to Cover the BIO-1000

RS Medical argues that the Secretary's finding that the BIO-1000 is not reasonable and medically necessary is substantively incorrect and cannot be based in substantial evidence. It points to the FDA approval of the device for marketing, the issuance of billing codes, and the extensive documentation it has submitted as evidence that the device is not experimental or investigative. The Secretary counters that she has significant discretion in applying the "not reasonable and necessary" exclusion; that FDA approval and the issuance of billing codes and fee schedules are not determinative of coverage; and that she considered the evidence offered by RS Medical and rejected it for reasons based on substantial evidence.

An agency's interpretation of its own regulations is normally entitled to substantial deference, particularly where the interpretation is part of "'a broad and highly technical regulatory program,' in which the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment based in policy concerns.'" *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994)(quoting *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 697 (1991)). However, where, as here, the subject agency has displayed an egregious and unexplained consistency, the decision is entitled to little or no

deference. *Malcomb*, 15 F.3d. at 369. Under standard deference, if an agency's "characterization is sustainable, it must be sustained." *Carle Found. Hosp. v. Shalala*, 57 F.3d 597, 599 (7th Cir. 1995). Here, the Secretary has offered two clearly conflicting characterizations by saying in many instances that the BIO-1000 is reasonable and medically necessary, but saying in others, including the decisions challenged here, that the BIO-1000 is experimental and investigational. In order to resolve the conflict, the Court will review the Secretary's characterizations side by side, so that it may sustain one and reject the other.

The Secretary's denials are based entirely in the required exclusion of coverage for devices determined to be "not reasonable and necessary" under 42 U.S.C. 1395y(a)(1)(A). "The Secretary's decisions as to whether a particular medical service is 'reasonable and necessary' . . . are clearly discretionary decisions." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). The Secretary has interpreted the term "reasonable and necessary" to mean that the item is "safe and effective," "not experimental or investigational," and "appropriate." *Medicare Program Integrity Manual*, Ch. 13, § 13.5.1. The relevant tests are "whether the service has been proven safe and effective based on authoritative evidence, or alternatively, whether the service is generally accepted in the medical community as safe and effective for the condition for which it is used." 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995).

1. *FDA Approval of the BIO-1000*

The decisions at issue discounted the FDA's approval of the BIO-1000, holding that FDA approval of the BIO-1000 does not necessitate a finding that the device is reasonable and medically necessary. The Secretary maintains that was appropriate because the FDA and CMS are separate entities. RS Medical contends not that FDA approval is binding on the Secretary for purposes of determining whether the device is reasonable and medically necessary, but only that it is meant to be utilized as evidence for evaluation of whether a device is "safe and effective" or "experimental and investigational." The Secretary "uses FDA categorization of a device as a factor in Medicare coverage decisions." 42 C.F.R. § 405.201(a)(1). The Secretary has stated that "CMS adopts FDA determinations of safety and effectiveness", but that "[a]lthough

an FDA-regulated product must receive FDA approval or clearance for at least one indication to be eligible for Medicare coverage, . . . FDA approval/clearance alone does not generally entitle a device to Medicare coverage." 68 Fed. Reg. 55634, 55636 (September 26, 2003).

The Council's challenged decisions here gave no weight to the FDA's approval of the BIO-1000 for the purpose of treating symptoms of osteoarthritis. In contrast, even the administrative law judge in the 535 decision, despite denying coverage, suggested that FDA approval supported a finding that the device was safe for its approved purposes. Similarly, other administrative law judges approving coverage gave at least some weight to FDA approval. *See* AR 20749, 20757 (noting that FDA determined BIO-1000 to be substantially equivalent to a TENS unit for safety purposes, but gave it its own efficacy determination). Three of the Council's challenged decisions instead treated FDA approval as a hurdle that must be cleared before a device can be considered for coverage, but failed to consider it other than in this light. AR 00011, 19202, 19213. The fourth, the 782 decision, apparently did not even consider FDA approval. However, the statement that "CMS adopts FDA determinations of safety and effectiveness" suggests approval is more than a mere prerequisite for coverage; it is evidence that the device was subjected to sufficient scrutiny to determine that it is safe and effective for the purposes indicated. While it is true that safety and effectiveness, by themselves, are not enough to mandate a finding that the device is reasonable and medically necessary, the criteria quoted above from the Medicare Program Integrity Manual make clear the Secretary's view that they should be given some weight in the decision. Thus, the Council's failure to give FDA approval any weight at all was arbitrary and capricious.

2. *Evidence of Acceptance in the Medical Community*

Beyond evaluating whether a device has been shown to be "safe and effective," the Secretary has also looked to whether a device is "not experimental or investigational" and whether it is "appropriate" in making coverage determinations. In evaluating these factors, the Secretary has held that the most important evidence, in order of preference, is:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
  - Scientific data or research studies published in peer-reviewed medical journals;
  - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
  - Medical opinion derived from consultations with medical associations or other health care experts.

Medicare Program Integrity Manual, § 13.7.1. Determinations are to take into account "the broad range of available evidence," and determinations "which challenge the standard of practice in a community and specify that an item is never reasonable and necessary, shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage." *Id.* The Secretary argues that the evidence submitted by RS Medical and Bionicare is not sufficient to establish that the BIO-1000 is not experimental or investigational and is appropriate. RS Medical maintains that the peer-reviewed articles submitted, in addition to the widespread actual use of and payment for the BIO-1000, clearly establish its acceptance and appropriateness.

The Council's findings that the BIO-1000 is experimental and investigational did fail to give sufficient weight to the evidence supporting its efficacy and widespread acceptance. To support its claims, RS Medical offered a number of studies published in peer-reviewed journals, as well as affidavits and medical records from a large number of prescribing physicians. After reviewing the studies submitted by RS Medical, the Council first noted that "throughout the record, the purpose of the BIO-1000 device has been described in a number of ways," including a generic description as a device that "alleviates the pain and other symptoms" of osteoarthritis and a more specific claim that "its use may ultimately result in regeneration of knee cartilage." 535 Decision at 10. The fact that the purposes of the device have been described in both general and specific terms does not by itself cut against a finding that it is reasonable and necessary.

With regard to the claim that the BIO-1000 stimulates cartilage growth, the Council quickly concurred with the administrative law judges' opinions that there was little objective evidence showing that the device

promoted regeneration of cartilage in *humans*. *Id.* The Council recognized that some studies on *animals* purported to show positive effects on cartilage, but decided that there was no basis in Medicare coverage standards for relying on such studies. *Id.* at 12. This was not unreasonable.

In contrast to this review of the animal studies on the merits, though, the Council made only a cursory review of the studies supporting the general effectiveness of the BIO-1000 for treatment of osteoarthritis. The Council found that the studies on human subjects were fatally compromised by their authors' ties to Bionicare, and did not assess them on their merits at all. The decisions quoted the following criterion for determining whether a device has achieved general acceptance in the medical community: "limited case studies distributed by sponsors with financial interest in the outcome [] are not sufficient evidence of general acceptance by the medical community." *Id.* at 8, *quoting Medicare Program Integrity Manual* (Pub. 100-08), Chapter 13, § 7.1. It then noted in dismissing the studies that not only were most of them authored at least in part by people with financial interests in Bionicare, but that others were supported by grants from Bionicare. *Id.* at 11. However, this is not in accord with even the criterion quoted; these were not limited studies *distributed* by the authors, not mere puffing, but rather studies *published in peer-reviewed journals*. As such, they deserved to be given at least some weight as authoritative evidence of the BIO-1000's acceptance within the medical community, as suggested by the determination criteria.

Further, the Council did not in the challenged decisions consider and evaluate "the broad range of available evidence." *Medicare Program Integrity Manual*, Ch. 13, § 7.1. The favorable administrative law judge decisions, in contrast, undertook a much more far-ranging review. *See* AR 20749, 20758, 20761 (stating that it is "simply wrong to state that no clinical evidence exists" for efficacy of BIO-1000), 20783-85 (recognizing symptoms which suggested appropriateness of therapy with BIO-1000 and recommending establishment as suggested coverage criteria for BIO-1000). In addition to the outcome of those reviews, the Court notes not only the studies, but the frequent payments made by Medicare itself, as well as evidence that more than 1,500 commercial payers and numerous Worker's Compensation plans have covered the device.

The BIO-1000 has been prescribed in all 50 states. Thus, taking into account the broad range of evidence available, the Secretary's finding that the BIO-1000 is not widely accepted as a treatment for osteoarthritis of the knee was not based on substantial evidence.

Given the evidence, in the form of FDA approval, that the BIO-1000 is safe and effective, and the additional evidence supporting the medical community's widespread acceptance of the BIO-1000 as a reasonable treatment for osteoarthritis, the favorable coverage decisions appear to be more based on substantial evidence than the denials at issue here. Further, given the frequent payments the Secretary has already made for its use, and the Secretary's failure in the challenged decisions to offer a reasonable explanation distinguishing between the circumstances there and the circumstances in the favorable decisions, this appears to be that "rare instance" where a change in interpretation must be rejected. The challenged decisions were arbitrary and capricious and not based on substantial evidence. They are hereby REVERSED.

C. Whether Liability Should be Limited

Because the Court has decided to invalidate the Secretary's denials of coverage for the BIO-1000, it does not reach the issue of whether the advance beneficiary notices provided by RS Medical were sufficient evidence of its knowledge that coverage would be denied, or whether RS Medical should have known denial was likely on any other basis. Similarly, the Court does not decide whether the second version of the notice was sufficient to inform beneficiaries that coverage denial was likely.

D. Payment

The only remaining issue is whether, as the Secretary argues, this Court should remand for payment in accordance with CMS procedures or, as RS Medical argues, CMS should be directed to pay 80% of the cost of each claim because the payment schedule for the BIO-1000 had not taken effect at the time of the subject claims.

The Secretary quotes convincing authority to the effect that remand is appropriate because there has been no final decision on payment that is subject to judicial review. Indeed, RS Medical offers only a half-

hearted claim that the Secretary should be required to pay 80% of the cost of RS Medical's charges. Because it is not entirely clear from the record whether any local payment schedules existed when the claims arose, the matter is REMANDED for payment in accordance with this opinion.

III. CONCLUSION

For the reasons stated above, Plaintiff RS Medical's motion for summary judgment [Dkt. # 65] is GRANTED, Defendant Secretary Kathleen Sebelius' cross-motion [Dkt. # 66] is DENIED.

IT IS SO ORDERED.

Dated this 28th day of July, 2009.

RONALD B. LEIGHTON
UNITED STATES DISTRICT JUDGE